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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/075,970	HELMUS, MICHAEL	
	Examiner	Art Unit	
	Melanie Tyson	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7,9-21,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-7,9-21,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Applicant's amendment received on 05 November 2007.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3, 5, 6, 9-21, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eury (5,443,458) in view of Bolz (6,287,332 B1). Eury discloses an implantable medical device (see entire document) comprising a biodegradable inner core material (18) and biodegradable covering materials (outer covering material 20 and inner covering material 22), wherein after insertion into a patient, the device becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. The covering material substantially controls the rate at which the inner core material becomes flexible upon contact with body fluids in that initially, fluid will contact the biodegradable covering material prior to contacting the

biodegradable inner core. The device is resorbed by the body within a period of time, thus the inner core material becomes increasingly flexible upon contact with body fluids. The covering material is a hydrophobic surface erodable polymer (polycaprolactone; for example, see column 4, line 26) and the covering materials comprise therapeutic agents (for example, see column 4, lines 43-56). Eury further discloses the device is balloon-expandable coronary stent (for example, see column 3, lines 19-30 and column 4, lines 43-56) comprising a tubular structure that is laser-cut (for example, see column 4, line 36 and Figures 1-2).

Eury discloses that the material employed for the inner core is selected for its ability to impart the necessary physical properties to the stent, specifically sufficient strength to maintain the patency of the vessel and sufficient flexibility to allow it to be balloon-expandable (for example, see column 3, line 54 – column 4, line 5), as well as being completely resorbed by the body. Eury further discloses that materials capable of performing both the structural function, as well as being resorbable are *typically* polymeric in nature. Although Eury fails to disclose the biodegradable inner core material is specifically a metallic material or a ceramic material, Eury discloses that various modifications may be made.

Bolz discloses an implantable medical device, such as a bioresorbable stent (see entire document). Bolz teaches constructing the bioresorbable stent of degradable metallic materials. Bolz further teaches that stents of degradable metallic material combine the advantageous mechanical properties of metal stents (such as elasticity, deformability, and stability by way of improving ductility, tensile strength, etc.; for

example, see column 3, lines 11-35) with the bioresorbability of polymer-based stents (for example, see column 2, lines 6-16). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a metallic material in the inner core of Eury as taught by Bolz. Doing so would provide desired mechanical properties for the stent of Eury.

Furthermore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to construct the biodegradable inner core of a metallic and a ceramic material. Applicant has not disclosed that a metallic or ceramic inner core provide an advantage, are used for a particular purpose, or solve a stated problem. Therefore, it would have been obvious to one of ordinary skill as a matter of design choice to modify the inner core material of Eury, such that the inner core material is a metallic or ceramic material. Furthermore, it is well known in the art to use metallic and ceramic materials in biodegradable stents (for example, see Litner's column 2, lines 64-67 and column 5, lines 15-21).

With further respect to claims 11-13, Eury discloses the inner core material comprises a tubular structure. Although Eury fails to disclose the inner core material comprises a monofilament core and a woven multifilament core, Eury discloses that various modifications may be made. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to construct the inner core comprising a monofilament core or a woven multi-filament core. Applicant has not disclosed that a monofilament core or a woven multi-filament core provide an advantage, are used for a particular purpose, or solve a stated problem. Therefore, it would have been obvious to

one of ordinary skill as a matter of design choice to modify the inner core of Eury, such that the inner core comprises a monofilament core or a woven multifilament core. Furthermore, biodegradable monofilament and woven multifilament stents are well known in the art (for example, see Litner's column 2, lines 64-67 and column 5, lines 24-26).

With further respect to claims 46 and 47, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the stent to have adequate rigidity from about three to about six months and that is completely biodegradable within about six months to one year following implantation, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eury in view of Bolz as applied to the claims above, and further in view of Langer (6,160,084). Eury in view of Bolz discloses a device as described above, however, fails to disclose the covering material is a shape memory biodegradable polymer. Langer discloses a biodegradable polymer for making a medical implant (see entire document). Langer teaches the biodegradable polymer is a shape memory biodegradable polymer so that the implant changes shape in reaction to changes in temperature (for example, see column 13, lines 26-29). Langer further teaches that changes in shape provide a way to utilize the device in a first shape intended for an initial use and then in a second shape intended for a subsequent use, which forms upon reaching body temperature (for example, see column 13, lines 19-25). Therefore, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to construct the covering material of shape memory biodegradable polymer as taught by Lagner in order to provide the stent with shape memory, thus facilitating deployment of the stent.

Response to Arguments

5. Applicant's arguments filed 05 November 2007 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art applied fails to teach or suggest each and every element claimed. Examiner respectfully disagrees.

Applicant argues that there is no teaching or suggestion in Eury that the covering materials are to be provided with characteristics (e.g., a sufficient thickness) that would allow these layers to substantially control the rate at which the inner core material becomes flexible upon contact with bodily fluid as claimed. However, this limitation is considered a functional limitation. Since Eury discloses the structural limitations as claimed (i.e., a biodegradable covering material having a thickness that covers the biodegradable inner core material), the covering material disclosed by Eury is capable of performing the function as claimed (i.e., controlling the rate at which the inner core becomes flexible).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 9-5:30 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
January 7, 2008

(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER